

DETAILED ACTION

Receipt is acknowledged of applicants' amendment and remarks, filed on 18 November 2011.

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Status of the Claims

In the amendment filed on 18 November 2011, claim 1 has been amended and claims 3-12 remain cancelled. Claims 1 and 2 are treated on the merits in this action. The following rejections are reiterated. They constitute the complete set presently being applied to the instant application.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 2 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2004/0009218 ("Kitamura") in view of U.S. Patent No. 6,677,142 ("Weissmuller") (both references were cited in the IDS filed on 23 February 2006) further in view of U.S. Patent No. 6,596,311 ("Dobetti") (see PTO-892).

Kitamura teaches a biodegradable article formed from an entirely linear amylose that has a weight average molecular weight of not less than 100 kDa (equivalent to a degree of polymerization of 615) (reading on amended claim 1) and has a narrow

molecular weight distribution, which is obtained by enzyme-synthesis using phosphorylase (reading on claim 2) (see p. [0020]).

Kitamura further explains that the disclosed biodegradable article is formed from enzyme-synthesized amylose using phosphorylase, wherein the enzyme-synthesized amylose is composed of glucose monomers exclusively bonded by alpha-1,4-glucosidic linkage (reading on claim 1) (see p. [0021]). The disclosed enzyme-synthesized amylose has a dispersity (M_w/M_n) of not more than 1.25 (see p. [0027]) (reading on claim 1).

Kitamura explains that the disclosed biodegradable article is beneficial in that it has excellent biodegradability, transparency, processability, and strength characteristics (see p. [0021]).

Kitamura teaches application of the disclosed biodegradable material in pharmaceuticals (see p. [0055] and p. [0060]), medical products (see p. [0060]), medical material (see p. [0063] and [0067]), and medical appliances (see p. [0063] and [0067]). However, Kitamura does not explicitly teach use of the biodegradable material in tablets.

Weissmuller teaches alpha-1,4-glucan chain containing polysaccharides (see col. 1, lines 11-13). The disclosed polysaccharides may be used as tablet fillers (see col. 6, lines 21-23).

Kitamura or Weissmuller do not explicitly teach use of the glucan containing polysaccharides as disintegrants, however, polysaccharides such as amylose are known disintegrants in the tableting art (see Dobetti, col. 4, lines 35-54).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a disintegrant for tablets consisting of an alpha-1,4-glucan having a degree of polymerization of not less than 180 and less than 1230 and a dispersity of not more than 1.25, as taught by Kitamura in view of Weissmuller further in view of Dobetti. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a product because it has excellent biodegradability, transparency, processability, and strength characteristics, as explained by Kitamura (see above).

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,759,316 ('316) in view of U.S. Patent No. 6,677,142 ("Weissmuller") further in view of U.S. Patent No. 6,596,311 ("Dobetti").

Although the conflicting claims are not identical, they are not patentably distinct from each other because '316 claims a biodegradable article formed from enzyme-synthesized amylose, wherein the enzyme-synthesized amylose is composed of glucose monomers exclusively bonded by alpha-1,4-glucosidic linkage, and the enzyme-synthesized amylose has a weight average molecular weight of not less than 100 kDa, and the enzyme-synthesized amylose has a molecular weight distribution of not more than 1.25 (claim 1). '316 does not explicitly teach use of the biodegradable material in tablets. Weissmuller teaches alpha-1,4-glucan chain containing polysaccharides (see col. 1, lines 11-13). The disclosed polysaccharides may be used as tablet fillers (see col. 6, lines 21-23). '267 or Weissmuller do not explicitly teach use of the glucan containing polysaccharides as disintegrants, however, polysaccharides such as amylose are known disintegrants in the tabletting art (see Dobetti, col. 4, lines 35-54). See 35 USC 103 rejection, above.

As such, a person of ordinary skill in the art at the time the instant application was filed would have found claims 1 and 2 of the instant application prima facie obvious over claims 1-12 of U.S. Patent No. 7,759,316 in view of U.S. Patent No. 6,677,142 ("Weissmuller") further in view of U.S. Patent No. 6,596,311 ("Dobetti").

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Response to Arguments

Applicants' arguments filed on 18 November 2011 have been fully considered but they are not persuasive.

Applicants argue that neither Kitamura nor Weismuller teach or suggest the use of alpha-1,4-glucan as a disintegrant; as such, these references are not relevant to the problem and results attained by the claimed invention. See remarks, page 3.

Examiner respectfully submits that Kitamura explicitly teaches use of the disclosed biodegradable material in pharmaceuticals (see [0055] and [0060]). The term "pharmaceuticals" is commonly used to describe, *inter alia*, oral dosage forms such as tablets and capsules. Additionally, Kitamura uses the polysaccharide being claimed; "[p]roducts of identical chemical composition cannot have mutually exclusive properties.' A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)." See MPEP 2112.01. As such, examiner respectfully submits that Kitamura is relevant to the problem and results attained by the claimed invention, as it is in the same field of endeavor.

Regarding Weissmuller, while the name "disintegrant" is not used to describe the disclosed alpha-1,4-glucan chain containing polysaccharide tablet filler, once the polysaccharide is added to the tablet, the disintegrating effect would be inherent since, as indicated above, "[p]roducts of identical chemical composition cannot have mutually exclusive properties.' A chemical composition and its properties are inseparable.

Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)." See MPEP 2112.01. As such, examiner respectfully submits that Weissmuller is also relevant to the problem and results attained by the claimed invention, as it is in the same field of endeavor.

Applicants argue that Dobetti does not explicitly teach the use of alpha-1,4 glucan having the claimed degree of polymerization. See remarks, page 3.

Examiner respectfully submits that Dobetti was invoked merely to show that amylose is explicitly taught as a disintegrant in tablets. The particular polysaccharide being claimed was taught by Kitamura. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that Dobetti's use of disintegrants such as crospovidone and maize starch shows that Dobetti teaches away from the use of other disintegrants and that Dobetti teaches towards use of natural starches or cross-linked PVPs. See remarks, pages 3-4.

Examiner respectfully submits that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See MPEP 2123. As noted in the substantive rejection, amylose is explicitly disclosed as a disintegrant. Additionally, it is noted that amylose is described as a "starch

derivative" (see col. 4, line 53) and is distinguished from natural starches, such as maize starch (see col. 4, line 47). As such, Dobetti explicitly states that the amylose disclosed is not a natural starch.

Applicants argue that applicants discovered that using the claimed disintegrant results in a disintegration time of 20-21 seconds irrespective of pH. See remarks, page 4.

Examiner respectfully submits that applicants have not shown that this result is unexpected. According to MPEP 716.02: Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). According to MPEP 716.02(a): "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue." *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). In Corkhill, the claimed combination showed an additive result when a diminished result would have been expected. This result was persuasive of nonobviousness even though the result was equal to that of one component alone. Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (i.e., demonstrating "synergism"). *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). However, a greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness because such an effect can either be expected or

unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. Ex parte The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991) (Evidence showing greater than additive sweetness resulting from the claimed mixture of saccharin and L-aspartyl-L-phenylalanine was not sufficient to outweigh the evidence of obviousness because the teachings of the prior art lead to a general expectation of greater than additive sweetening effects when using mixtures of synthetic sweeteners.).

Regarding the obviousness-type double patenting rejection, applicants argue that Kitamura is directed to a biodegradable article formed from enzyme-synthesized amylose as opposed to the disintegrant being claimed instantly. See remarks pages 5-6.

Examiner respectfully submits that Kitamura does not preclude use of the claimed material as a disintegrant. Additionally, the obviousness-type double patenting rejection was based on a combination of Weissmuller and Dobetti, which teach use of starch derivatives such as amylose in tablets and explicitly as disintegrants, respectively, as indicated in the substantive rejection. Finally, as noted above, Kitamura uses the polysaccharide being claimed; “[p]roducts of identical chemical composition cannot have mutually exclusive properties.’ A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).” See MPEP 2112.01.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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